INVESTOR RISKS

BiPAD® SURGICAL
ENHANCED SURGICAL ERGONOMICS

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Risks Related to BiPAD, Inc., Business

We are dependent upon the success of our current product, and we do not yet have U.S. regulatory clearance for our products. We cannot be certain that any of our products will receive regulatory clearance or approval or that any of our products, will be commercialized in the United States. If we are unable to commercialize our products in the United States, or experience significant delays in doing so, our ability to generate revenue will be significantly delayed or halted, and our business will be harmed.

We have expended significant time, money and effort in the development of our current products. If we are not successful in commercializing our products, or if FDA clearance or approval of any of our products is significantly delayed, we may never generate substantial revenue, our business, financial condition and results of operations would be materially and adversely affected, and we may be forced to cease operations. We intend to commence sales of our products in [2017], but sales may not meet our expectations. We may be required to spend significant amounts of capital or time to respond to requests for additional information by the FDA [or foreign regulatory bodies] or may otherwise be required to spend significant amounts of time and money to obtain FDA clearance or approval and foreign regulatory approval.

Our products may never gain any significant degree of market acceptance, and a lack of market acceptance would have a material adverse effect on our business.

We cannot assure you that our products will gain any significant degree of market acceptance among physicians or patients, even if necessary regulatory and reimbursement approvals are obtained. We believe that recommendations by physicians will be essential for market acceptance of our products; however, we cannot assure you that any recommendations will be obtained. Physicians will not recommend the products unless they conclude, based on clinical data and other factors, that the products represent a safe and acceptable alternative to other available options. In particular, physicians may elect not to recommend using our products.

If our competitors have products that are approved in advance of ours, marketed more effectively or demonstrated to be more effective than ours, our commercial opportunity will be reduced or eliminated and our business will be harmed.

The market for electrocautery products is competitive. Competitors include a variety of public and private companies that currently offer or are developing cardiac surgery products generally and automated anastomotic systems specifically that would compete directly with ours.

We believe that the primary competitive factors in the market for medical devices used in the treatment of coronary artery disease include:

- improved patient outcomes;
- access to and acceptance by leading physicians;
- product quality and reliability;
- ease of use;
- device cost-effectiveness;
- training and support;
- novelty;

- physician relationships; and

- sales and marketing capabilities.

We may be unable to compete successfully on the basis of any one or more of these factors, which could have a material adverse effect on our business, financial condition and results of operations.

Surgeons, who have been using pedal activated electrocautery instruments for their entire careers, may be reluctant to consider alternative technologies, despite potential advantages. Any resistance to change among practitioners could delay or hinder market acceptance of our products, which would have a material adverse effect on our business.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, clinical trials, obtaining regulatory clearance or approval and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies ~~and therapies~~ that are more effective, better tolerated or less costly than any that we are developing or that would render our product candidates obsolete and noncompetitive. Our competitors may succeed in obtaining clearance or approval from the FDA and foreign regulatory authorities for their products sooner than we do for ours.

We have limited manufacturing experience and may encounter difficulties in increasing production to provide acceptable levels of quality assurance and/or an adequate supply to customers.

To date, our manufacturing activities have consisted primarily of producing limited quantities of our products for use in clinical studies. We do not have experience in manufacturing our products in the commercial quantities that might be required to market our products in the United States. Production in commercial quantities will require us to expand our manufacturing capabilities and to hire and train additional personnel. We may encounter difficulties in increasing our manufacturing capacity and in manufacturing commercial quantities, including:

- maintaining product yields;

- maintaining quality control and assurance;

- providing component and service availability;

- maintaining adequate control policies and procedures; and

- hiring and retaining qualified personnel.

Difficulties encountered in increasing our manufacturing could have a material adverse effect on our business, financial condition and results of operations.

The manufacture of our products is a complex and costly operation involving a number of separate processes and components. In addition, the current unit costs for our products, based on limited manufacturing volumes, are very high, and it will be necessary to achieve economies of scale to become profitable. Certain of our manufacturing processes are labor intensive, and achieving significant cost reductions will depend in part upon reducing the time required to complete these processes. We cannot assure you that we will be able to achieve cost reductions in the manufacture of our products and, without these cost reductions, our business may never achieve profitability.

We have considered, and will continue to consider as appropriate, manufacturing in-house certain components currently provided by third parties, as well as implementing new production processes. Manufacturing yields or costs may be adversely affected by the transition to in-house production or to new production processes, when and if

these efforts are undertaken, which would materially and adversely affect our business, financial condition and results of operations.

Our manufacturing facilities, and those of our suppliers, must comply with applicable regulatory requirements. Failure to obtain regulatory approval of our manufacturing facilities would harm our business and our results of operations.

Our manufacturing facilities and processes will be subject to periodic inspections and audits by various U.S. federal, U.S. state and foreign regulatory agencies. Our failure to maintain necessary regulatory approvals for our manufacturing facilities could prevent us from manufacturing and selling our products.

Additionally, our manufacturing processes and, in some cases, those of our suppliers are required to comply with FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic inspections by governmental agencies, including FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of product distribution or other operating restrictions, seizures or recalls of our device and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to market and sell our products, our business may be harmed.

We are in the beginning stages of building a sales and marketing organization, and we have limited experience as a company in the sales, marketing and distribution of our products. To promote our ~~current and future~~ products in the United States and Europe, we must develop our sales, marketing and distribution capabilities or make arrangements with third parties to perform these services. Competition for qualified sales personnel is intense. Developing a sales force is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our products. To the extent that we enter into arrangements with third parties to perform sales and marketing services, our product revenue may be lower than if we directly marketed and sold our products. We expect to rely on third-party distributors for substantially all of our international sales. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable.

We expect to be dependent upon a number of key suppliers, the loss of which would materially harm our business.

We use or rely upon sole source suppliers for certain components and services used in manufacturing our products, and we utilize materials and components supplied by third parties with which we do not have any long-term contracts. In recent years, many suppliers have ceased supplying raw materials for use in implantable medical devices. We cannot assure you that materials required by us will not be restricted or that we will be able to obtain sufficient quantities of such materials or services in the future. Moreover, the continued use by us of materials manufactured by third parties could subject us to liability exposure. Because we do not have long-term contracts, none of our suppliers is required to provide us with any guaranteed minimum production levels.

We may in the future be a party to patent litigation and administrative proceedings that could be costly and could interfere with our ability to sell our products.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. We may become a party to patent infringement claims and litigation or interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions. The defense and prosecution of these matters are both costly and time consuming. Additionally, we may need to commence proceedings against others to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel.

┼We are aware of patents issued to third parties that contain subject matter related to our technology. We cannot assure you that these or other third parties will not assert that our products and systems infringe the claims in their patents or seek to expand their patent claims to cover aspects of our products and systems.┼ An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities or require us to seek licenses. In addition, if we are found to willfully infringe third-party patents, we could be required to pay treble damages in addition to other penalties. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may be required to redesign our products to avoid infringement, and it may not be possible to do so effectively.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

We rely upon patents, trade secret laws and confidentiality agreements to protect our technology and products. Our pending patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we have obtained or will obtain in the future might be invalidated or circumvented by third parties. If any challenges are successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. To the extent that our intellectual property protection is inadequate, we are exposed to a greater risk of direct competition. In addition, competitors could purchase any of our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. If our intellectual property is not adequately protected against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants and advisors to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us be kept confidential and not disclosed to third parties except in specific circumstances and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We could be exposed to significant product liability claims, which could be time consuming and costly to defend, divert management attention, and adversely impact our ability to obtain and maintain insurance coverage. The expense and potential unavailability of insurance coverage for our company or our customers could adversely affect our ability to sell our products, which would adversely affect our business.

The testing, manufacture, marketing, and sale of our products involve an inherent risk that product liability claims will be asserted against us.

Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and adversely affecting our financial condition and operating results.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of our systems. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may choose not to use or to discontinue using our systems and potential customers may opt against purchasing our systems due to the cost or inability to procure insurance coverage.

We are dependent upon key personnel, loss of any of which could have a material adverse effect on our business.

Our future business and operating results depend significantly on the continued contributions of our key technical personnel and senior management, including those of our co-founder, CEO and President, Louis G. Cornacchia, M.D. These services and individuals would be difficult or impossible to replace and none of these individuals is subject to a post-employment non-competition agreement. While we are subject to certain severance obligations to Dr. Cornacchia, either he or we may terminate his employment at any time and for any lawful reason or for no reason. Our business and future operating results also depend significantly on our ability to attract and retain qualified management, manufacturing, technical, marketing, sales and support personnel for our operations. Competition for such personnel is intense, and there can be no assurance that we will be successful in attracting or retaining such personnel. ~~[~~Additionally, although we have key-person life insurance in the amount of $___.0 million on the life of Dr. Cornacchia, we cannot assure you that this amount would fully compensate us for the loss of Dr. Cornacchia's services. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, could materially adversely affect our business, financial condition and results of operations.

We currently lack a source of product revenue. We may not become profitable.

Our ability to become and remain profitable depends upon our ability to generate product revenue. Our ability to generate significant continuing revenue depends upon a number of factors, including:

- achievement of U.S. regulatory clearance or approval for our additional products;
- successful sales, manufacturing, marketing and distribution of our products~~.~~

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our research and development programs or commercialization efforts.

Our development efforts have consumed substantial capital to date. We believe that our existing cash, cash equivalents and short-term investments, together with the net proceeds from this offering, will be sufficient to meet our projected operating requirements through at least the next [18] months. Because we do not anticipate that we will generate significant product revenue for the foreseeable future, if at all, we will need to raise substantial additional capital to finance our operations in the future. Our future liquidity and capital requirements will depend upon, and could increase significantly as a result of, numerous factors, including:

- market acceptance and adoption of our products;
- our revenue growth;
- ~~the progress of clinical trials;~~
- the timing and costs of regulatory submissions;
- the timing and costs required to receive both domestic and international governmental approvals;
- the timing and costs of new product introductions, if FDA clearance or approval is obtained;

- the extent of our ongoing research and development programs; and

- the costs of developing marketing and distribution capabilities.

Until we can generate significant continuing revenue, if ever, we expect to satisfy our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any corporate collaboration and licensing arrangements may require us to relinquish valuable rights. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our commercialization efforts or one or more of our research and development programs.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. The revenue we generate, if any, and our operating results will be affected by numerous factors, many of which are beyond our control, including:

- the rate of physician adoption of our products;

- the introduction by us or our competitors, and market acceptance of, new products;

- the results of regulatory and reimbursement actions;

- the timing of orders by distributors or customers;

- the expenditures incurred in the research and development of new products; and

Evolving regulation of corporate governance and public disclosure will result in additional expenses and continuing uncertainty.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over our affairs.

Following the completion of this offering, our executive officers, current directors and holders of five percent or more of our common stock will beneficially own 100% of the voting rights to and approximately 85% of our common stock, We expect that upon the closing of this offering, that same group will continue to hold a majority of our outstanding common stock. Therefore, even after this offering, these stockholders will likely be able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, and delay product development.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to return our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the section entitled," "Risk Factors" contains forward-looking statements. Forward-looking statements include all statements that are not statements of historical facts and may relate to, but are not limited to, expectations of future operating results or financial performance, capital expenditures, introduction of new products, regulatory compliance, plans for growth and future operations, as well as assumptions relating to the foregoing. These risks and other factors include, but are not limited to, those listed under "Risk Factors." In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "continue" or the negative of these terms or other similar terminology. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These statements represent only management's beliefs and assumptions as of the date of this prospectus, and actual events or results may differ materially.

We believe that it is important to communicate our future expectations to potential investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause actual events or results to differ materially from the expectations expressed in or implied by our forward-looking statements. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we do not plan to publicly update or revise any forward-looking statements after we circulate investment information to potential investors, whether as a result of any new information, future events or otherwise. Potential investors should not place undue reliance on our forward-looking statements. Before you invest in our Company, you should be aware that the occurrence of any of the adverse events described in the "Risk Factors" section and elsewhere in this prospectus could harm our business, prospects, operating results and financial condition. You should read here and in the documents that we reference with the understanding that we cannot guarantee future results, levels of activity, performance or achievements.